



[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The invention listed below is owned by an agency of the U.S.

Government and is available for licensing to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

FOR FURTHER INFORMATION CONTACT: Peter Soukas, J.D., 301-594-8730; peter.soukas@nih.gov. Licensing information and copies of the patent applications listed below may be obtained by communicating with the indicated licensing contact at the Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases, 5601 Fishers Lane, Rockville, MD, 20852; tel. 301-496-2644. A signed Confidential Disclosure Agreement will be required to receive copies of unpublished patent applications.

SUPPLEMENTARY INFORMATION: Technology description follows.

Live Attenuated Zika Virus Vaccine

Description of Technology:

This application claims live attenuated Zika viruses and vaccines, attenuated chimeric Zika viruses and vaccines, and multivalent immunogenic compositions comprising Zika vaccines and vaccines for other flaviviruses. The chimeric Zika viruses claimed include a first nucleotide sequence encoding at least one structural protein from a Zika virus (ZIKV), a second nucleotide sequence encoding at least one nonstructural protein from a first flavivirus, and a third nucleotide sequence of a 3' untranslated region from a second flavivirus. The multivalent immunogenic compositions claimed comprise an attenuated ZIKV vaccine or an attenuated chimeric ZIKV vaccine (or their combination) together with one or more of a first attenuated virus that is immunogenic against dengue serotype 1, a second attenuated virus that is immunogenic against dengue serotype 2, a third attenuated virus that is immunogenic against dengue serotype 3, and a fourth attenuated virus that is immunogenic against dengue serotype 4. The present disclosure also claims methods of inducing immune responses, as well as preventing ZIKV and another flavivirus, e.g., dengue virus.

Such a chimeric vaccine candidate may induce a humoral (antibody) and T-cell response to ZIKV, while the nonstructural proteins of dengue virus will likely induce a T-cell response. The dengue platform also contains a deletion in the TL2 stem-loop structure of the 3' untranslated region (UTR), called $\Delta 30$ and $\Delta 30/31$ attenuating mutations. The $\Delta 30$ deletion has proven to be one of the defining characteristics of the

successful one dose dengue vaccine, which is currently in a large scale (17,000 patient) clinical trial in Brazil.

This technology is available for licensing for commercial development in accordance with 35 U.S.C. 209 and 37 CFR part 404, as well as for further development and evaluation under a research collaboration.

Potential Commercial Applications:

- Diagnostics
- Vaccines

Competitive Advantages:

- One-dose vaccine
- Ease of manufacture
- Can be included in multivalent flavivirus vaccines

Development Stage:

- In vivo data available (animal)

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Intellectual Property: HHS Reference No. E-118-2016/0, U.S. Provisional Patent Application Number 62/307,170, filed March 11, 2016, PCT Patent Application TBA filed March 11, 2017.

Licensing Contact: Peter Soukas, J.D., 301-594-8730; peter.soukas@nih.gov.

Collaborative Research Opportunity: The National Institute of Allergy and Infectious Diseases is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize norovirus

diagnostics or vaccines. For collaboration opportunities, please contact Peter Soukas, J.D., 301-594-8730; peter.soukas@nih.gov.

Dated: April 12, 2017.

Suzanne Frisbie

Deputy Director

Technology Transfer and Intellectual Property Office

National Institute of Allergy and Infectious Diseases

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